

CERTIFICATE OF ANALYSIS

Complement Technology, Inc.
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Tyler, Texas 75703, USA

Product: **C5/FB-Dpl**
Catalog # **A355 Lot #**
Exp. Date:

Description: Complement C5 and Factor B (fB)-Depleted Human Serum made by immunoaffinity chromatography

<u>Specifications</u>	<u>Limits</u>	<u>Results</u>
PROTEIN CONCENTRATION	≥40 mg/mL employing an extinction coefficient of E1%/280nm = 10.0	65 mg/mL
FILL VOLUME	0.50 – 0.55 mL	0.52 mL
PHYSICAL APPEARANCE	Clear, straw colored	Conforms
BUFFER	Phosphate buffered saline, pH 7.3	Conforms
PRESERVATIVE	None, filtered through a 0.22 µm pore size filter.	Conforms

CLASSICAL PATHWAY (CP) FUNCTIONAL ACTIVITY (CH50) *

NHS Std	≥ 75 CH50/mL	170 CH50/mL
Un-constituted C5/FB-Dpl	≤ 10 CH50/mL	< 1.0 CH50/mL
Ratio $\frac{\text{CH50/mL C5/FB-Dpl} \times 100}{\text{CH50/mL NHS Std}}$	≤ 10%	< 1%
Reconstituted C5/FB-Dpl (+ 0.075mg C5 & 0.2mg FB/mL)	≥ 60 CH50/mL	152 CH50/mL
Ratio $\frac{\text{CH50/mL C5/FB-Dpl} + \text{C5 \& FB} \times 100}{\text{CH50/mL NHS Std}}$	≥ 60%	89%

ALTERNATIVE PATHWAY (AP) FUNCTIONAL ACTIVITY (AP50) **

NHS Std	≥ 50 AP50/mL	167 AP50/mL
Input NHS Std to yield 1 APH50	≤ 20 µL	6 µL
Un-constituted C5/FB-Dpl	≤ 10 AP50/mL	< 1 AP50/mL
Ratio $\frac{\text{AP50/mL C5/FB-Dpl} \times 100}{\text{AP50/mL NHS Std}}$	≤ 10%	< 1%
Reconstituted C5/FB-Dpl (+ 0.075mg C5 & 0.20mg FB/mL)	≥ 50 AP50/mL	139 AP50/mL
Input C5/FB-Dpl with C5 & FB to yield 1 AP50	≤ 20 µL	7.2 µL
Ratio $\frac{\text{AP50/mL C5/FB-Dpl} + \text{C5 \& FB} \times 100}{\text{AP50/mL NHS Std}}$	≥ 60%	83%

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Complement C5/FB-Depleted Human Serum, Lot 2 (Continued)

IMMUNOCHEMICAL ANALYSIS

Ouchterlony	No C5 or Factor B antigen detectable using various dilutions of anti-Human C5 & anti-Human Factor B antiserum	Conforms
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STARTING MATERIAL: HUMAN SERUM/PLASMA

HBsAg 3.0	Negative	Negative
Anti-HIV 1 and 2 Plus O	Negative	Negative
Anti-HCV 3.0	Negative	Negative
HIV-1/HCV/HBV by NAT	Negative	Negative
West Nile Virus (WNV) by NAT	Negative	Negative
Anti-Syphilis	Negative	Negative
Zika RNA NAT	Negative	Negative
Anti-HBc	Negative	Negative
Anti-HTLV I/II	Negative	Negative

SAFETY PRECAUTIONS: This product is derived from human blood and although it tested negative for HIV antibodies and Hepatitis B and C it should be handled with appropriate precautions including wearing gloves and safety glasses.

* One unit of classical pathway activity (CH50) is defined as the input of C5/FB-Dpl or C5/FB-Dpl reconstituted with purified C5 and Factor B, or NHS Complement Standard yielding 50% lysis of 1×10^8 EA when incubated for 60 minutes at 37°C in a total reaction volume of 1.5 mL GVB⁺⁺.

** One unit of alternative pathway activity (APH50) is defined as the input of C5/FB-Dpl or C5/FB-Dpl reconstituted with purified C5 and Factor B or NHS Complement Standard yielding 50% lysis of 1.5×10^7 rabbit erythrocytes (Er) when incubated for 30 min. at 37°C in a total reaction volume of 100µL GVB^o containing a final Mg-EGTA concentration of 5 mM.

STORE AT -70°C or BELOW. Avoid Repeated Freeze/Thaw
Thaw quickly at 37°C, mix, and put in an ice+water bath to cool.
FOR RESEARCH USE ONLY NOT FOR HUMAN OR DRUG USE

Signature of Analyst

Date of Analysis